Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Alleged Delay in Diagnosis and Treatment at a Community Based Outpatient Clinic Tennessee Valley Healthcare System Nashville and Murfreesboro, Tennessee

Report No. 11-02828-52

December 15, 2011

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections evaluated allegations of a delay in Graves' disease diagnosis and treatment at a community based outpatient clinic of the Tennessee Valley Healthcare System (the System).

We substantiated that there was about a 6-week delay in initiating the appropriate work-up of a patient's hyperthyroidism. However, this delay did not cause a delay in treatment that harmed the patient or negatively impacted his outcome. We also found that other System providers failed to notify the patient of both abnormal and normal test results in a timely manner.

We recommended that the System Director require that providers ordering laboratory, radiographic, and other tests and studies inform patients of test results and arrange for appropriate follow-up according to policy.

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendation and provided an acceptable action plan. We will follow up on the planned actions until they are completed.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Mid South Healthcare Network (10N9)

SUBJECT: Healthcare Inspection – Alleged Delay in Diagnosis and Treatment, at a Community Based Outpatient Clinic, Tennessee Valley Healthcare System, Nashville and Murfreesboro, Tennessee

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an evaluation in response to allegations of a delay in the diagnosis of Graves' disease and treatment at a community based outpatient clinic (CBOC) of the Tennessee Valley Healthcare System (System). The purpose of this inspection was to determine the validity of the allegations.

Background

The System is comprised of the Nashville and Alvin C. York (Murfreesboro) VA medical centers (VAMCs) and nine CBOCs. The CBOC, which is the subject of the allegations, is part of Veterans Integrated Service Network (VISN) 9. The CBOC employs contract staff to provide primary care services. The contract specifies that services be delivered in accordance with The Joint Commission standards and Veterans Health Administration (VHA) policies and procedures. In fiscal year 2010, the CBOC had over 4,000 unique primary medical care enrollees with approximately 15,000 visits.

Graves' disease is the most common form of hyperthyroidism, occurring when the immune system produces antibodies that stimulate the thyroid gland, causing it to overproduce the hormone thyroxine. Because thyroid hormones control metabolism, they are critical for regulating mood, weight, and mental and physical energy levels. Excessive thyroid hormone levels frequently build over an extended period, sometimes years, before Graves' disease is diagnosed. Symptoms can be non-specific for Graves' disease and develop so gradually that they can be confused with other health problems.

These symptoms include insomnia, fatigue, rapid or irregular heartbeat, tremors, anxiety, goiter,[1] weight loss, and bulging or dry eyes.

In April 2011, a former CBOC patient made clinical and administrative allegations to the OIG. Specifically, the complainant alleged that in February 2009 he told his CBOC primary care provider (provider) that he did not feel well, but the provider kept telling him his "blood work was fine." The complainant alleged that he still felt "odd" and self-referred himself to the Murfreesboro VAMC where he was "immediately diagnosed with Graves' disease." The complainant alleged that because his CBOC provider failed to diagnose his Graves' disease, he did not receive timely treatment. He stated that he did not want to "risk his health" by receiving further care there. He told the OIG that he elected to transfer his primary care to Murfreesboro VAMC but was denied travel reimbursement because primary care services were available at the CBOC.

Scope and Methodology

We conducted telephone interviews with the complainant, CBOC and medical center providers and patient advocates, and a treating endocrinologist at the System. We reviewed the patient's medical record, local and VHA policies, clinical practice guidelines, the CBOC contract, and the local Primary Care-Endocrinology Service agreement.

In general, OHI does not address complaints related to beneficiary travel pay. In this report, we focused on the patient's clinical care as it related to his thyroid condition.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Case Summary

The patient is a male veteran in his mid-60s with a history of diabetes, hypertension, osteoarthritis, and post-traumatic stress disorder. In 2005, the patient moved from the West Coast to Tennessee and enrolled for care at the System's Murfreesboro VAMC.

In August 2006, the patient transferred his care to the CBOC as the CBOC was located closer to his home. From 2007–2008, the patient saw a primary care NP an average of twice per year. His chief complaints were primarily knee pain, post-traumatic stress disorder exacerbation, and blurred vision. The provider conducted routine physical examinations, ordered appropriate laboratory tests and imaging studies, and consulted specialists as needed.

[1] A goiter is enlargement of the thyroid gland.

In February 2009, the patient complained to his primary care provider of worsening knee pain and tremors in both hands. The provider documented that there were no changes in weight or appetite, vision, or bowel habits; no anxiety or goiter; and regular heart rhythm. The provider consulted the Murfreesboro Orthopedic Service, ordered blood work to include thyroid function tests (TFTs), and renewed the patient's hypertension and diabetes medications. The provider also prescribed a 30-day supply of propranolol, a beta-blocker used to treat tremors, angina, high blood pressure, and several other conditions. The patient was given a 6-month follow-up appointment.

Two days after the patient's visit, a clinic staff member documented "Lab on providers [sic] desk due to abnormalities." The patient's T4 (free thyroxine) level was high at 4.4 ng/dL (reference range is .89–1.76 ng/dL) and his thyroid stimulating hormone (TSH) was low at .03 µIU/L (reference range is .35–5.50 µIU/L). The patient's medical record did not contain any further progress notes or orders by the provider after the mid-February primary care appointment.

In March 2009, the patient self-referred to the Murfreesboro VAMC for primary care services, telling his new primary care physician (PCP) that he was dissatisfied with the CBOC. During his initial Murfreesboro VAMC clinic visit, the PCP reviewed and discussed the patient's abnormal TFT results. The PCP also documented that the patient said he took his diabetes medication that morning but did not eat, and is "now tremulous." The patient reported that he was not taking his propranolol and he complained of "off and on" palpitations and chest pain. The PCP ordered a thyroid ultrasound (US)[2] and blood work to include TFTs and glucose levels. The PCP also changed the patient's hypertension medication and scheduled a 3-month follow-up appointment.

At his 3-month follow-up visit in June 2009, the PCP told the patient that the thyroid US revealed a thyroid nodule[3] and that his TFTs remained abnormal. The PCP consulted the Nashville VAMC Endocrinology Service via the computerized patient record system (CPRS) the same day.

An endocrinologist evaluated the patient approximately 10 days later, diagnosing him with thyrotoxicosis[4] and documenting that he potentially had Graves' disease. Additional testing confirmed the diagnosis of Graves' disease, and the endocrinologist notified the patient of this in late July during a follow-up appointment. The patient was continued on thyroid medication with a plan to biopsy his thyroid nodule once his thyroid hormone levels normalized. In November 2009, the patient underwent a fine-needle aspiration of the thyroid nodule. A negative result was available in CPRS 4 days later. During an Endocrinology Service appointment in late January 2010, the patient was informed that

[2] An imaging technique used for diagnosing suspected thyroid disease.
[3] A small lump of tissue that can be either benign (non-cancerous) or malignant (cancerous).
[4] Condition resulting from excessive production of thyroid hormones.

the nodule was non-cancerous and treatment options were discussed. The patient elected to undergo radioactive iodine ablation.[5] He is currently being followed by Nashville VAMC Endocrinology Service and is in stable condition.

Inspection Results

The complainant alleged that the CBOC provider did not diagnose his Graves' disease, and as a result, he (the patient) did not get timely treatment and did not feel comfortable returning to the CBOC for further care. While it is accurate that the provider did not make the diagnosis, further work-up was needed after the abnormal TFT results to confirm Graves' disease. Because the patient was changing providers during this time, the provider would not have had the clinical information needed to diagnose Graves' disease. However, the provider did not follow-up on the abnormal TFTs in accordance with local policy.

Issue 1: Delay in Diagnosis and Treatment

We determined that there was an approximately 6-week delay in initiating work-up of the patient's hyperthyroidism and subsequent treatment. We found that the CBOC provider did not follow up on the February 2009 abnormal TFTs.

The provider told us that he referred the patient to Endocrinology Service; however, this referral is not documented in the medical record. The provider told us that he did not take any further action because he believed the patient would not be returning to the CBOC.

The patient did not present with many of the classic symptoms of a thyroid condition. Nevertheless, he did complain of tremors. The provider ordered TFTs, prescribed propranolol to reduce the tremors, and scheduled a follow-up appointment for 6 months.

The provider received the abnormal TFT results on his desk 2 days later but we found no documented evidence that the provider noted the abnormal thyroid results, planned further workup, or notified the patient. We also found no documentation that the patient was given instructions for reporting medication effectiveness (i.e. propranolol) or side effects back to the provider, or what to do when he finished the 30-day supply of propranolol prescribed. VHA policy states that ordering providers are responsible for initiating appropriate clinical actions and following up on the orders they have placed.[6]

The patient told us that when he "self-referred" back to the Murfreesboro VAMC, he was "immediately diagnosed with Graves' disease." Medical record documentation reflects that once the Murfreesboro PCP assumed responsibility for the patient's care in late March, appropriate work-up testing and follow-up occurred. The Graves' disease

[5] Removal of thyroid tissue by treatment with radiation-emitting iodine.
[6] VHA Directive 2003-043, *Ordering and Reporting Patient Test Results*, dated August 6, 2003.

diagnosis was confirmed after completion of the work-up, which was more than 3 months after the patient's initial appointment with the Murfreesboro PCP. Despite the delay in diagnosis of Graves' disease, we found no evidence of harm attributable to this delay.

Issue 2: Patient Notification of Test Results

We noted during the course of our inspection that other providers failed to notify the patient of both abnormal and normal test results in a timely manner. VHA policy requires that ordering providers relay test results to patients no later than 14 calendar days from the date on which the results were available to the practitioner.[7] We found that:

- The Murfreesboro VAMC PCP did not notify the patient for more than 2 months that the thyroid US, completed in mid-April, was abnormal (revealed a nodule).[8]

- The Nashville VAMC endocrinologist did not notify the patient for more than 2 months that the thyroid biopsy, completed in mid-November, was benign.[9]

Timely communication of diagnostic test results to patients facilitates their involvement in care, decreases unnecessary duplicative testing, contributes to safe care by ensuring timely review of all results by clinicians, and demonstrates respect and concern for patients' well-being. A lack of knowledge about test results can be a source of considerable anxiety to patients and families.

Conclusions

We substantiated that there was a delay in initiating work-up of the patient's hyperthyroidism and subsequent treatment. When the Murfreesboro PCP assumed responsibility for the patient's care, appropriate work-up testing and follow-up occurred. We did, however, conclude that the delay did not harm the patient or negatively impact his outcome.

During the course of our review, we found that other providers failed to notify the patient of both abnormal and normal test results in a timely manner as required by policy.

Finally, we concluded that earlier follow-up than 6 months was indicated after beginning propranolol treatment for a tremor.

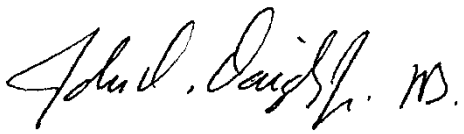
[7] VHA Directive 2003-043, *Ordering and Reporting Patient Test Results*, dated August 6, 2003; and VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009.
[8] Non-notification of abnormal test results was also cited in OIG Report No. 11-0003-186, *Alleged Delay in Diagnosis and Communication Issues, Chattanooga Community Based Outpatient Clinic, Tennessee Valley Healthcare System, Nashville, Tennessee*, June 8, 2011
[9] Non-notification of normal test results was also cited in OIG Report No. 11-00030-160, *Combined Assessment Program Review of the Tennessee Valley Healthcare System, Nashville, Tennessee*, May 5, 2011.

Recommendation

We recommended that the System Director require that ordering providers inform patients of test results and arrange for appropriate follow up according to policy.

Comments

The VISN and System Directors agreed with the findings and recommendation (see Appendixes A and B, pages 7–10, for the full text of their comments). The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 28, 2011

From: Director, VA Southeast Network (10N7)

Subject: **Healthcare Inspection –** Alleged Delay in Diagnosis and Treatment, Nashville, TN

To: Director, Atlanta Office of Healthcare Inspections Division (54AT)

Director, Management Review Service (VHA CO 10)

1. I concur with the report and have no comments

2. Should you need additional information, please contact Tammy Williams, VISN 9 Continuous Readiness Coordinator at (615) 695-2200.

(original signed by:)

John Dandridge, Jr.
Director, VA Mid South Healthcare Network (10N9)

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 28, 2011

From: Medical Center Director (626/00)

Subject: **Healthcare Inspection –** Alleged Delay in Diagnosis and Treatment, Nashville, TN

To: Director, VISN 9 (10N9)

I concur with the Office of Inspector General's inspection report and have no comments.

(o*riginal signed by:)*
Juan A. Morales, RN, MSN
Director, Tennessee Valley Healthcare System (626/00)

Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1.We recommended that the System Director require that ordering providers inform patients of test results and arrange for appropriate follow up according to policy.

Concur **Target Completion Date:** January 15, 2012

An effective address to this recommendation will be undertaken through a phased process. The tracking and notification of test results is a complex process, involving multiple Services and existing and non-existing CPRS components.

Phase 1: The current TVHS policy Procedure for Reporting Test Results (626097-11-16) will be reviewed and updated to ensure compliance with VHA Directive 2009-019, Ordering and Reporting Test Results. Physicians, and other staff as appropriate, will be notified of the policy revision and educated about the updates by the Chief of Staff Office. In addition, providers will be reminded of their responsibility to notify Veterans of both normal and abnormal lab results within 14 days. A sampling of records will be reviewed for compliance during Phase 1 with results reported to the Quality Executive Board.

Target Completion Date: November 15. 2011

Phase 2: A Nashville Primary Care Clinic will be identified as the pilot program for Phase 2. Currently available software and other CPRS options will be evaluated in the identified clinic for effectiveness in tracking patient tests and triggering patient notification. A Primary Care Notification template will be uploaded into CPRS for physician use in validation of veteran notification of test results. The template will document telephone notification, in-person notification or will generate a letter with test results that will be mailed to the veteran. This process will be re-evaluated in 90 days for compliance with OIG recommendations. TVHS will collect data on adherence to and timeliness of reporting through random audit of medical records.

Target Completion Date: February 1, 2012

Phase 3: TVHS has been selected as a pilot site for the VISN initiative for implementation of system-wide notification of patient lab values. TVHS will participate and monitor as directed.

Target Completion Date: TBD

Phase 4: Patient notification of diagnostic tests will occur via secure messaging in MyHealtheVet.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720
Acknowledgments	Audrey Collins-Mack, RN, FACHE, Project Leader Victoria Coates, LICSW, MBA Robert Yang, MD, Medical Consultant

Appendix D

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